Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

93211d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 7, 2002

Michael T. Lucas, President
North Coast Fisheries, Inc.
3230 Sebastopol Road
P.O. Box 8219
Santa Rosa, CA 94507-1219

WARNING LETTER

Dear Mr. Lucas:

On November 15, 16, 19, 20, 26 and December 13, 2001, we inspected your seafood processing facility, located at Pier 45 Shed D-3, San Francisco, CA. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your Scombroid species fin-fish to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

The serious deviations were as follows:

1. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations (temperature , signs of decomposition, and adequacy of ice) at the receiving critical control point to control histamine formation during the dates of inspection (11/15-16/01, 11/19-20/01, and 11/26/01).

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor:

   a. Condition and cleanliness of food-contact surfaces with sufficient frequency to ensure control, as evidenced by FDA's findings of *Listeria monocytogenes* in the swabs of the following areas of your processing facility on November 26, 2001:

- Walk-in cooler air curtain
- Plastic handcart in walk-in cooler
- Metal scale
- Plastic cutting boards supporting scale, filleting table
- Table with ice, filleting table
- Cleaned tote

b. Prevention of cross-contamination.
   - Specifically, an employee was observed using the ice shovel stored on the processing room floor to scoop clean ice on top of processed fish without washing or sanitizing in between. An employee was observed placing the ice shovel in the garbage can and then using it to scoop ice on top of processed fish without washing or sanitizing in between.
   - Two employees were observed chewing gum and spitting on the processing room floor on 11/26/01.

c. Maintenance of hand-washing and hand-sanitizing facilities.
   - There was no hot water for hand-washing on 11/15/01.
   - There were no paper towels for hand-drying on 11/16/01.
   - One of the hand-washing sinks in the processing room drains directly onto the floor.
   - Employees do not use hand sanitizers after hand-washing.
   - There was no hand-sanitizing station in the processing room. When one was installed on 11/20/01, employees did not use it after hand-washing.
   - Your firm was unaware of the concentration of the sanitizing agents used in the processing room or how to use them. It is imperative that you know the correct concentration and correct use of the sanitizing agents, since it is through the use of these agents that you rid your processing area of bacterial pathogens.

During FDA review of the inspection report for histamine-forming fin-fish, we noted the following items that need to be brought to your attention:

a. Your HACCP plan for fin-fish (ciguatera and histamine) should specify that "internal" temperature, rather than just product temperature is to be monitored at receiving. In addition, the monitoring procedures should state that a representative number of the largest fish will be monitored.

b. A HACCP plan cannot include two unrelated hazards, as in the case of your plan for fin-fish (ciguatera and histamine). Since your hazard analysis for these types of fin-fish indicated that you are the secondary processor and that the primary processor addressed the potential for ciguatera poisoning, you may delete reference to ciguatera in this plan.

c. If you are also a primary processor of histamine-forming species of fish, then you will need to develop a separate HACCP plan. In this case, you will need to

include harvest vessel controls at the receiving critical control point. See p. 88 of Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. A copy of this chapter is enclosed for your ready reference.

d. Please note that we have not reviewed your HACCP plans for other seafood commodities. It is your responsibility to ensure that these plans are in FDA compliance.

e. Please note that you should use the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 for information and guidance on developing and/or revising your HACCP plans.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Mr. Peter Pomilia, Vice President. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We acknowledge correspondence from your firm faxed by Danny Martinez on December 27, 2001 in which you respond to Form FDA 483 dated 12/13/01. You state that temperature and cooling media are checked daily and records are available. You must also check for and record signs of decomposition as stated in your HACCP plan. Some of your other responses were not specific and quite general in nature. You have initiated a new component to your sanitation program by having [redacted] conduct bi-monthly inspections and analytical testing for environmental contaminants.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Charles D. Moss, Acting for

Dennis K. Linsley
District Director
San Francisco District

Enclosure:

Handout on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

Form FDA 483

Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001

cc: Peter Pomilia, Vice President
Pier 45 Shed D-3
P.O. Box 471719
San Francisco, CA 94147